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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/333,256	06/15/99	ENGEL	PH05001579/2

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TRAN. 5	EXAMINER
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ART UNIT 1615	PAPER NUMBER
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05/15/01

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Advisory Action

Application No.
09/333,256

Applicant(s)
Engel et al.

Examiner
Susan Tran

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 7, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on May 7, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or conclusion for allowance
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

4. ☐ Applicant's reply has overcome the following rejection(s):
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachment
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: _____
Claim(s) objected to: _____
Claim(s) rejected: 1-6
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other:

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ATTACHMENT

Receipt is acknowledged of applicants Fee and Declaration filed 9/9/99, Requested for Extension of Time filed 08/28/00 and 05/07/01, Amendment A filed 08/28/00, Amendment B filed 10/24/00, and Notice of Appeal filed 05/07/01.

Response to Arguments

1. Applicant's arguments filed 05/07/01 have been fully considered but they are not persuasive. The examiner maintains the original rejection and thus claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al. US 5,905,149 ('149), in view of Eugster et al. US 5,593,691 ('691).

Applicant argues that Battistini is silent with respect to formulations capable of providing stable sources of cyclophosphamide. However, the burden is placed upon the applicant to establish that Battistini's cyclophosphamide formulation is not a stable formulation.

Applicant argues that Battistini provides no example of tablets comprising cyclophosphamide. However, Battistini is relied upon for the teaching within the four walls patent. Battistini cannot be limited to his best mode as described in the examples.

Applicant further argues that Battistini does not teach a film-coated tablet exclusive of preswollen starch, e.g. corn starch. Contrary to the applicant's argument, a review of the reference indicates in column 11, lines 1-29, a film-coating tablet. Applicant's specification

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examples suggest the use of starch, especially example 2 (using 0.200 mg of cornstarch). It is the position of the examiner that Battistini's starch and applicant's starch is substantially equivalent.

Applicants argued that Eugster does not teach a composition excluding preswollen starch. Eugster uses cornstarch, and thus, it is the position of the examiner that Eugster's starch and applicant's starch is substantially equivalent absent the presentation of some unusual and/or unexpected result that accrues from the claimed limit since Eugster teaches the composition has excellent stability and bioavailability of the active substances (column 8, lines 40-48); and the use of stabilizers to improve stability of the composition (column 22, lines 5-10).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


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